

In re Application of: LEWIN A.S. et al.  
Confirmation No: 6548  
Application No.: 10/808,042  
Examiner: WHITEMAN, B.

### REMARKS

Claims 1-23 are pending in the application. Claims 4-6, 10 12,13 and 16-22 have been withdrawn as being directed to non-elected subject matter. The elected claims are merely to comply with the Restriction Requirement and is not to be construed as surrender of any subject matter in the instant application. Claims, 1, 9 and 23 have been amended to direct entry of SEQ ID NO: 3. No new matter has been added by virtue of these amendments and entry is respectfully requested. Applicants hereby reserve the right to pursue the subject matter of the canceled claims in one or more divisional patent applications.

### *Claim Rejections Under 35 U.S.C. § 102*

Claims 1-3, 7-9, 14-15 are rejected under 35 U.S.C. § 102(b) as being anticipated by Lewin et al. (W0200066780).

Applicants respectfully traverse. However, in order to expedite prosecution, Applicants have amended claims 1, and 9 to be directed to SEQ ID NO: 3. As per the Examiner, SEQ ID NO: 3 remains free of the art.

However, Applicants submit that the active ribozyme of wherein the cleavage takes place is different to the cited reference and the targets are completely different. Cleavage takes place at position 154 of the HSV UL20 in the instant invention. The Examiner alleges that structural features were not discussed, however, Applicants submit that discussion of the differences in the ribozymes covered the fact that the structures are different.. Applicants respectfully submit, that it is known in the art that ribozymes are specific for a specific target, that is no two ribozymes can have the same structure, e.g. active site and cleave different sequences. As such the structural similarities, at the very least, the active sites are very small. For example, Applicants teach on page 2, lines 16-20:

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Accordingly, the invention features a ribozyme that specifically cleaves a target RNA sequence encoded by a HSV gene essential or important for efficient HSV replication or packaging. The gene can be, e.g., UL20, UL30, UL54, or ICP4. The ribozyme can be in a hammerhead configuration, within a vector, and/or within a cell. Examples of such ribozymes include those including SEQ ID NOs: 1, 3, 5, and/or 6.

On page 3, lines 19-25:

The invention provides ribozymes that specifically cleave a target RNA sequence encoded by an HSV gene essential for replication. The RNA targeted can be any that is essential or important for HSV replication, e.g., one that encodes a protein necessary for efficient genome replication or viral assembly. Exemplary targets include RNAs encoding UL20, UL30, UL54 and ICP4. To inhibit replication of HSV in a cell, ribozymes against 1, 2, 3, 4 or more such targets can be used. It is preferred that at least 2 or 3 different ribozymes be used simultaneously to prevent mutation rendering ribozyme resistance.

Applicants submit that the ribozymes are different in that they each are specific for different targets and cleave at different locations. None of these sequences can be anticipated by the cited reference as each sequence is highly specific for a target. As such, the cited reference fails to teach each and every claim limitation. Applicants' amendment of claims 1 and 9 are not to be construed as surrender of any subject material. Applicants hereby reserve the right to pursue the cancelled or amended subject matter in one or more continuation or divisional applications. No new matter has been added by virtue of these amendments and entry is respectfully requested.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

Claims 1-3, 7-9, 14-15 were rejected under 35 U.S.C. 102(e) as being anticipated by Lewin et al. (US 20050096282).

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Applicants respectfully traverse. However, in order to expedite prosecution, Applicants have amended claims 1, and 9 to be directed to SEQ ID NO: 3. As per the Examiner, SEQ ID NO: 3 remains free of the art.

As discussed above, ribozymes are target specific. The Examiner alleges that structural features were not discussed, however, Applicants submit that discussion of the differences in the ribozymes covered the fact that the structures are different.. Applicants respectfully submit, that it is known in the art that ribozymes are specific for a specific target, that is no two ribozymes can have the same structure, e.g. active site and cleave different sequences. As such the structural similarities, at the very least, the active sites are very small. The cited reference discusses ribozymes and targets which are completely different to the instant invention, i.e. the ribozyme from the cited reference could not function as in the instantly claimed invention and vice versa. As such, the cited reference does not teach each and every claim limitation and fails as a reference. Applicants have amended claims 1, and 9 which are now directed to SEQ ID NO: 3. The amendments are not to be viewed as surrender of any subject matter. Applicants hereby reserve the right to pursue the amended or cancelled subject matter in one or more continuation or divisional applications. No new matter has been added by virtue of these amendments and entry is respectfully requested.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

Claim 23 is rejected under 35 U.S.C. § 102(b) as being anticipated by Horsburgh et al. (US 6,277,621).

Applicants respectfully traverse.

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Applicants have amended claim 23 to include SEQ ID NO: 3. Amendment of the claims is not to be construed with surrender of any subject matter. Applicants hereby reserve the right to pursue the cancelled or amended subject matter in one or more continuation or divisional applications. Applicants teach a ribozyme-resistant cell for producing a HSV expression vector encoding an anti-HSV ribozyme, the cell comprising at least one nucleotide sequence encoding a portion of an HSV gene, the nucleotide sequence having been modified to not be cleavable by the ribozyme. Horsburgh et al. are directed to virus production. As such, Horsburgh et al. fail to teach each and every claim limitation and fails as a reference.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

### **CONCLUSION**

Applicants respectfully request entry of the foregoing remarks and reconsideration and withdrawal of all rejections. It is respectfully submitted that this application with claims 1-3, 7-9, 14-15 and 23 define patentable subject matter and is in condition for allowance. Accordingly, Applicant respectfully requests allowance of these claims.

Applicants have made every effort to present claims which distinguish over the cited art, and it is believed that all claims are now in condition for allowance. However, Applicants request that the Examiner call the undersigned (direct line 561-671-3666) if anything further is required by the Examiner prior to issuance of a Notice of Allowance for all claims.

This response is being filed within the shortened statutory period and as such no extension of time or fees are due. Although, Applicants believe that no extensions of time or fees are due, please consider this submission as a petition for any retroactive extension of time needed. The Commissioner for Patents and Trademarks is hereby authorized to charge the amount due for a one month retroactive extension of time and any deficiency in any fees due with

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the filing of this paper or credit any overpayment in any fees paid on the filing, or during prosecution of this application to Deposit Account No. 50-0951.

Respectfully submitted,  
AKERMAN SENTERFITT



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Nicholas A. Zachariades, Ph.D.  
Reg. No. 56,712  
AKERMAN SENTERFITT  
P.O. Box 3188  
West Palm Beach, FL 33402-3188  
Tel: 561-653-5000

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